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PRODUCT CHEMISTRY REVIEW OF: AN END-USE PRODUCT [X]

DP BARCODE :D339746 RECEIVED DATE 09/MAY/2007 FILE SYMBOL: 264-RNAG

PRODUCT NAME : SC 547 Herbicide MRID: 470703-09 ACTION CODE: R01.0

COMPANY NAME: Bayer CropScience, LP FOOD USES [X]

PPC NUMBER OF THE TGAI IN THE PRODUCT: 015804 DECISION NO.: :378455

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8/18/08 8114108

TO: 23 Joanne Miller/Hope Johnson
Herbicide Branch/RD (7505P)

INTRODUCTION:

The primary review of subject product was conducted by the Pest Management Regulatory Agency/Canada (PMRA). The Pesticide Safety Directorate/UK (PSD) was the lead country in conducting the primary reviews of Thien carbazon-methyl technical and Cyprosulfamide safener that was treated as a TGAI. Our secondary/peer reviews of all products were incorporated in reporting tables and uploaded into circa. All primary and peer reviews can be downloaded from circa, a site restricted only to members with user IDs and passwords using the following web site:

<http://circa.europa.eu/Members/irc/sanco/Home/main>

This memorandum applies to subject end-use product focusing on data gaps and/or additional requirements as entered in circa's reporting tables. Our reviews in the reporting tables focused on the requirements by the product chemistry discipline as per OPPTS Test Guidelines, Series 830. Other primary or peer reviews were indicated, in the reporting tables, as non-applicable or not required by the product chemistry discipline. In support of this application, the applicant submitted product chemistry data, MRID #470703-01C, a basic CSF dated 17/JAN/2007, a proposed label, Formulator's Exemption Statement, Certificate With Respect to Citation of Data, and Data Matrix.

Group "A" and "B" OPPTS Test Guidelines Series 830:

Except for the requirements listed in this memorandum, the remaining requirements pertaining to Group "A" and "B" of OPPTS Test Guidelines, Series 830, Product Properties, for subject product have been fulfilled and are adequate.

DATA GAPS:

1. The applicant should be advised to submit product's storage stability and corrosion characteristics, when complete, two product chemistry data requirements of GRNs #830.6317 & 830.6320, respectively.

2. The proposed Isocratic HPLC analytical method, AM003405KF1, entitled: "Determination of Thiencarbazone-methyl (BYH 18636) Tembotrione (AE F0172747), and isoxadifen-ethyl (AEF122006) in technical and formulated products by Isocratic HPLC". The method will need to be validated by the EPA's laboratory. The applicant should be advised to submit a copy of the method and samples to EPA's laboratory for validation at the following address: EPA's Analytical Chemistry Laboratory, 701 Mapes Road, Fort Meade, Maryland 20755-5350.

Product's Label:

1. SC 547 Herbicide will be used for weed control in crops (field corn, sweet corn, popcorn, and corn grown for silage).
- 2a. The subject product contains 5.6% Thiencarbazone-methyl, Reg. No. 264-RNAN, in the form of Methyl 4[[[4,5-dihydro-3-methoxy-4z-methyl-5-oxo-1H-1,2,4-triazol-1-yl)carbonyl]amino]sulfonyl]-5-methyl-3-thiophenecarboxylate, 97.6% pure, CAS #317815-83-1. In addition, the product contains 28.3% an unregistered Tembotrione Technical, Reg. No. 264-ILO, plus [REDACTED] the safener, isoxadifen-ethyl. The PMRA was the lead country in conducting the primary reviews for subject end-use product.
- 2b. After satisfying the five batch analysis for thiencarbazone-methyl reflecting commercial scale production (refer to Reg. No. 264-RNAN) and if the nominal concentration was found to be different from 97.58%, the applicant will need to submit a revised label and CSF for subject product with an upgraded nominal concentration of the active ingredient.
- 3a. The applicant should be advised to list, in product's label, a statement pertaining to "The Physical or Chemical Hazards."
- 3b. The label ingredient statement that reads "Inert Ingredients" must be corrected to read "Other Ingredients."

Products Basic CSF dated 22/FEB/2007

- 1a. The proposed basic CSF dated 17/JAN/2007 was filled out correctly and completely and agree with the label claim nominal concentration as per the regulations of PR Notice 91-2. Further, the upper and lower certified limits are within the standard limits of 40CFR§158.175(b)(2).
- 1b. The composition of the product is identical to that reviewed by PMRA, the primary reviewer of this product. The composition, however, reflects pilot plant production.

- 1c. All ingredients claimed in the proposed basic CSF dated 17/JAN/2007 have been approved for use in pesticide formulations intended for food uses provided the use falls within the safener's (isoxadifen-ethyl) restrictions as per 40CFR§180.570.

CONCLUSIONS:

The TRB has no objections for a conditional registration of subject product as per FIFRA sec. 3(c)(7). The submitted label and CSF dated 17/JAN/2007 are acceptable.

After registration of the two technical sources, thiencarbazone methyl (Reg. No. 264-RNAN) and tembotrione technical, Reg. No. 264-ILO, plus resolving the two data gaps above, #'s 3(a) & 3(b) under product's label, the TRB will have no objections for acceptance of a revised label/CSF and granting an unconditional registration of subject product as per FIFRA sec. 3(c)(5).

Note to RM:

Please note Findings 2(b) under Product's Label and 1(c) under Product's CSF.above.